

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rudnick et al.

Examiner: D. Isabella

Serial No.: 09/271,304

Group Art Unit: 3738

Filed: March 17, 1999

Docket: 498-67 CON 2

For: NESTED STENT

Dated: May 16, 2000

Date _____ Label No. _____
I hereby certify that on the date indicated above I
deposited this paper or fee with the U.S. Postal Service
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Name (Print)

(Signature)

Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION OF PRIOR INVENTION IN
THE UNITED STATES TO OVERCOME A PATENT UNDER 37 C.F.R. § 1.131

Sir:

1. We, James J. Rudnick, and Dominik M. Wiktor, both citizens of the United States, residing respectively at 11 Clearwater Court, Mahwah, NJ 07430 and 6441 3rd Palm Point, Saint Petersburg, Florida 33706-2123, are joint inventors of the above-identified application.

2. At the time of the invention thereof we were working for Meadox Medicals, Inc., assignee of the present application. With respect to the inventor Rudnick, I was an employee of Meadox Medicals, Inc. and with respect to inventor Wiktor, I was a consult

for Meadox Medicals, Inc. We submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to April 1, 1994, i.e. the effective date of U.S. Patent No. 5,876,432, Lau et al. (hereinafter the '432 patent), which was cited by the Examiner in an Office Action mailed December 29, 1999.

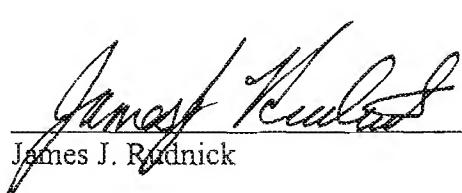
3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention was completed in the United States before April 1, 1994 which is a date earlier than the U.S. filing date of the '432 patent. Completion of the invention prior to April 1, 1994, is shown by conception and actual reduction to practice of the invention as evidenced by construction and testing of a nested stent.
4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to April 1, 1994, the following documents being submitted as evidence:
 - a. A Meadox Medicals, Inc. invention disclosure (Exhibit A) bearing dates signed by the inventors and dates signed by witnesses prior to April 1, 1994, the filing date of the '432 patent. (The dates have been redacted to prevent their unnecessary disclosure.) That invention disclosure describes the nested stent of the present invention where the benefits of the device are described as follows: "all of the above being accomplished by providing maximum monofilament wire density in a minimum volume of space by proper nesting of convolutions of formed wire over a mandrel." In an attachment to that invention disclosure, a drawing of the nested

stent is shown. The drawing shown in the attachment to the invention disclosure is substantially similar to the drawings shown in Figures 2 and 8 of the present application. This invention disclosure evidences conception of the invention prior to April 1, 1994.

- b. A confidential report entitled "Stent Analysis Summary" (Exhibit B) prepared by Product Genesis Inc., an engineering and design firm, which was retained by assignee, Meadox Medicals, Inc., to conduct an engineering analysis of the nested stent which is the subject of the claims of the present application. That report bearing a final issue date prior to April 1, 1994 (also redacted), includes a drawing labeled Figure 2-2 "Stacked Packing Geometry" showing a drawing of the nested stent of the present invention. Further and as evidence of completion of the invention, the report of Exhibit B includes photographs at Figures 4-4 through 4-7 showing the constructed nested stent of the present invention. Also as an attachment to this report are two spreadsheets showing design variables for construction of the nested stent of the present invention. Certain of these design variables have been included in the present application, being incorporated into Table 1.
5. The materials submitted herewith establish that the invention was completed, i.e. conceived and reduced to practice at a date prior to April 1, 1994, the filing date of the '432 patent.

6. This declaration is submitted in a response to a first Office Action issued by the Examiner and is therefore believed to be timely filed.
7. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: MAY 17, 2000



James J. Rudnick

DATED: _____

Dominik Wiktor

A

MEADOX MEDICALS, INC. INVENTION DISCLOSURE

1. GIVE TITLE OF YOUR IDEA:

HI-STRENGTH HI-WIRE DENSITY INTRAVASCULAR EXPANDABLE STENT

2. DESCRIBE YOUR IDEA IN DETAIL AND INCLUDE SKETCH AND FORMULA IF NECESSARY:

Intraluminal Stent characterized by its ability to resist external compressive forces, also to discourage encroachment of cell ingrowth between wires after deployment, yet maintain full flexibility; all of the above being accomplished by providing maximum monofilament wire density in a minimum volume and space, by proper nesting of convolutions of formed wire over a mandrel

3. STATE ADVANTAGES OVER EXISTING PRODUCTS OR METHODS:

Presently used and known Stents, specifically as shown in US Pat 4,886,062 by Wiktor, although similar in design and basic construction do not provide high strength nor tight wire nesting as the Stent of this Invention.

4. ATTACH AND IDENTIFY COPIES OF ALL KNOWN REFERENCES, DRAWINGS, SKETCHES, DESCRIPTIONS, DATA, ARTICLES, TEXTBOOKS, ETC. (Note: All entries made in Laboratory Notebooks, memoranda, correspondence or similar documentation by author, recipient, date, project number, book number, and page number, if applicable. Concept Meeting,

First memo to J.Rudnick , subsequent meeting at MEADOX Dominik M. Wiktor developed thus reduced a theoretical idea to a working model; several models constructed and expanded over a balloon, additional samples constructed and together with a memo sent to MEADOX

5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT: Dominik M. Wiktor James J.Rudnick Brent Nixon

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
		Dominik M. Wiktor	4 Culin Drive Cranford, NJ 070
		James Rudnick	74 Moore Ave, Waldwick, NJ 07463

WITNESSED AND UNDERSTOOD BY:

Signature Anthony M. Soadaro Print Name Date: _____

APPROVED FOR FURTHER PATENT REVIEW:

<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____	Date: _____
<input type="checkbox"/> Yes	<input type="checkbox"/> No	_____	Vice President Date: _____

EXECUTIVE COMMITTEE REVIEW:

<input type="checkbox"/>	Approved for Patentability Opinion	_____	President	Date: _____
<input checked="" type="checkbox"/>	Approved for Patent Application		President	Date: _____
<input type="checkbox"/>	Other (explain below)	_____	President	Date: _____

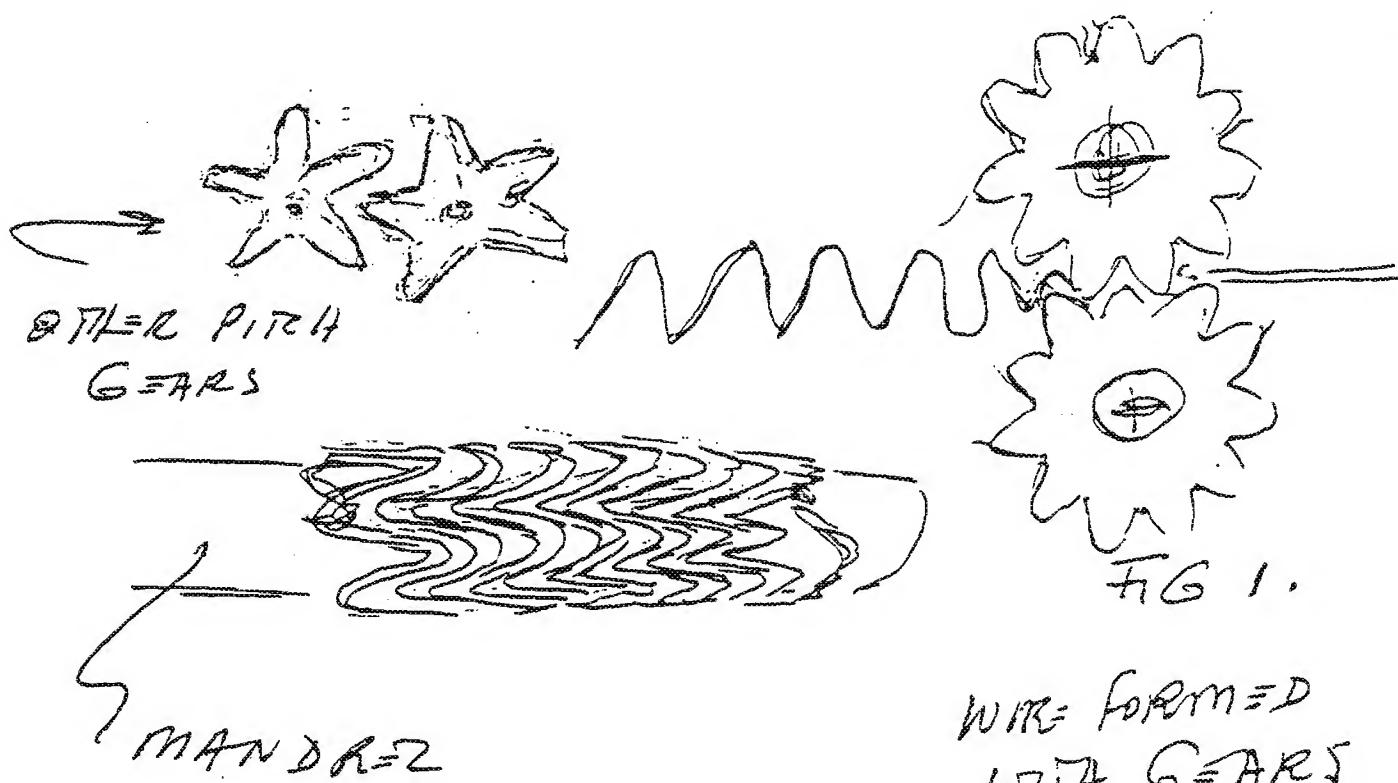
Comments: _____

BOOK NO.:	PAGE NO. <u>1</u> of <u>1</u>	PROJECT NO.:	DATE:
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SUBJECT:

HIGH STRENGTH - HIGH WIRE DENSITY
INTRAVASCULAR EXPANDABLE STENT

1. TANTALUM WIRE PREFORMED OVER GEARS



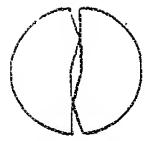
James J. Rudnick
JAMES J. RUDNICK

BY
RECORDED

Dominick M. Nikton
DOMINICK M. NIKTON

Cathy McFadden
CATHY MCFADDEN

EACH PAGE MUST BE SIGNED, WITNESSED, AND DATED.



Product Genesis Inc.

Engineering Design and Product Development

300 Bent Street
Suite 200
Cambridge, MA 02141
617 661 3552
FAX 617 661 0126

Stent Analysis Summary

FINAL ISSUE

For:
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112 Bauer Drive
Oakland, NJ 07436
1-800-221-1542

By:
Product Genesis, Inc.
300 Bent Street, Suite 200
Cambridge, MA 02141
617-661-3552

CONFIDENTIAL

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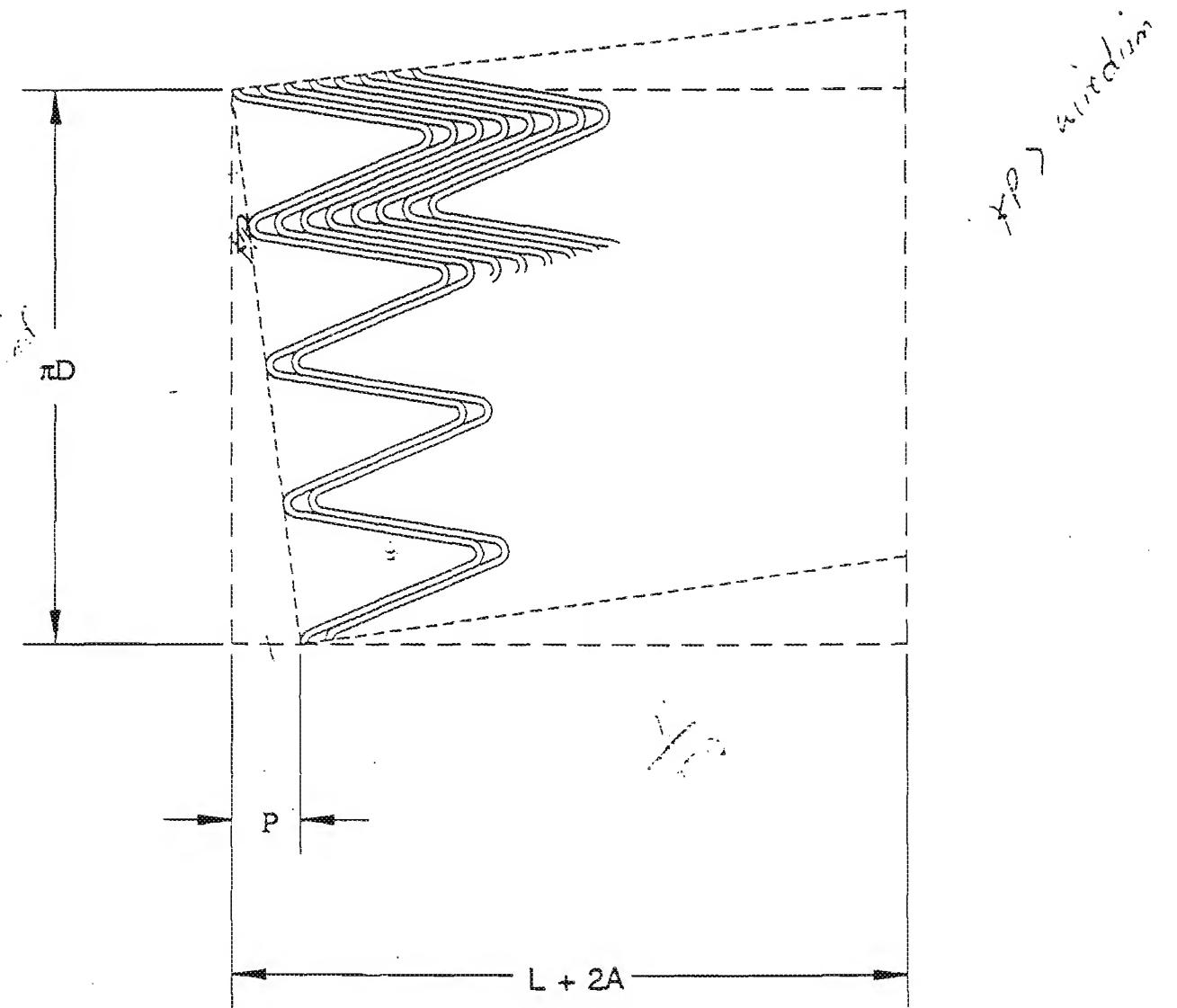


Figure 2-2: Stacked Packing Geometry

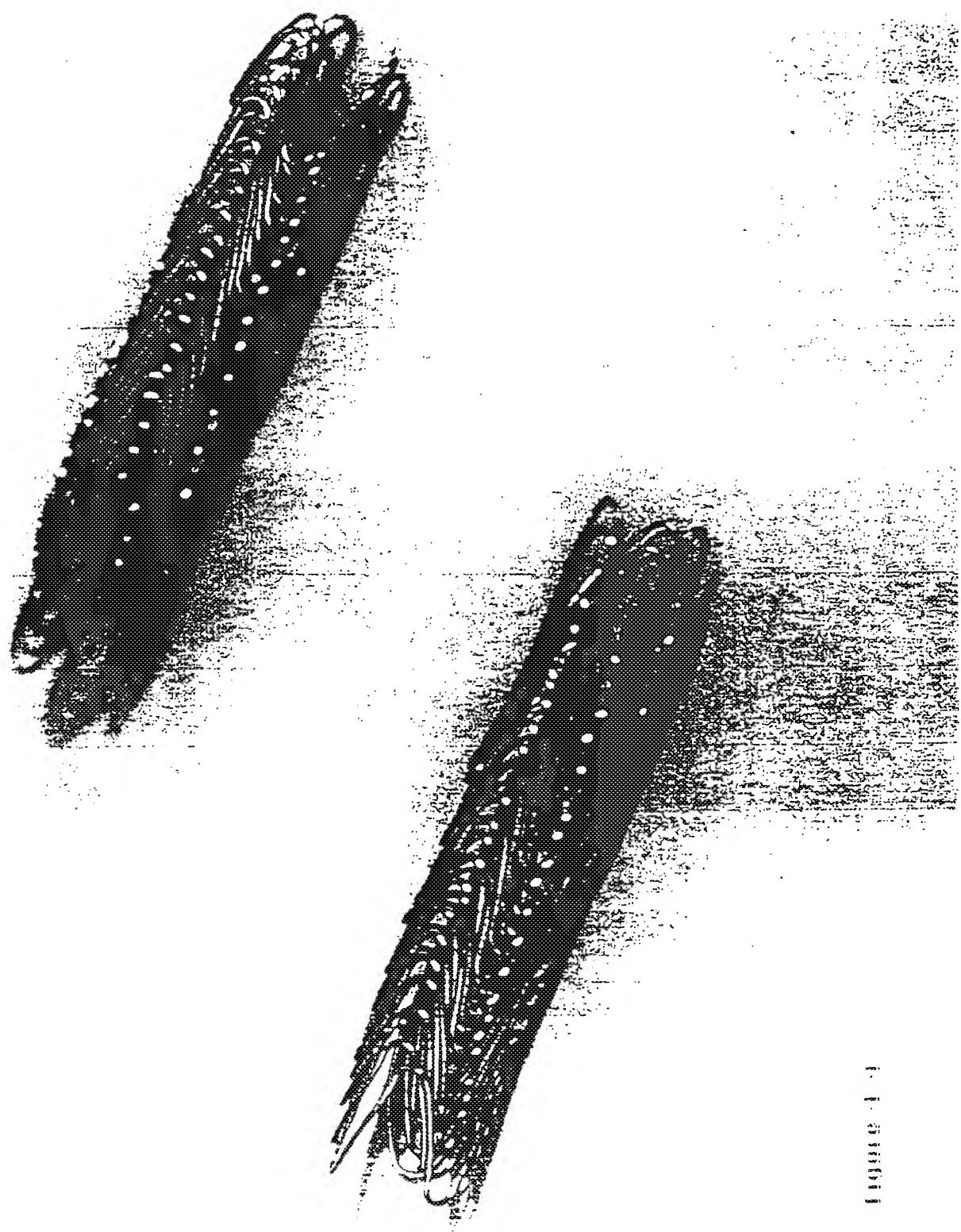


Figure 1

Figure 1-5

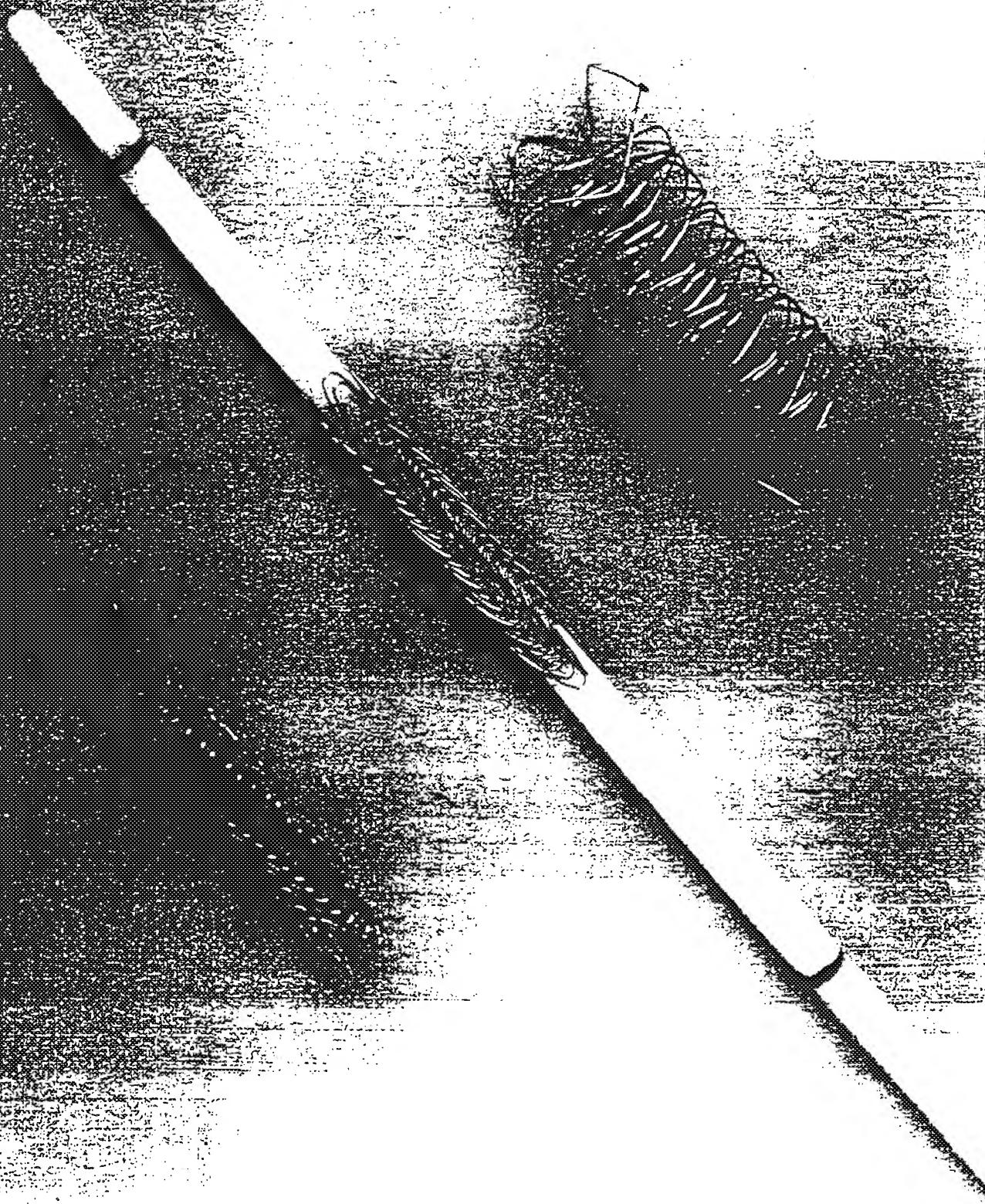
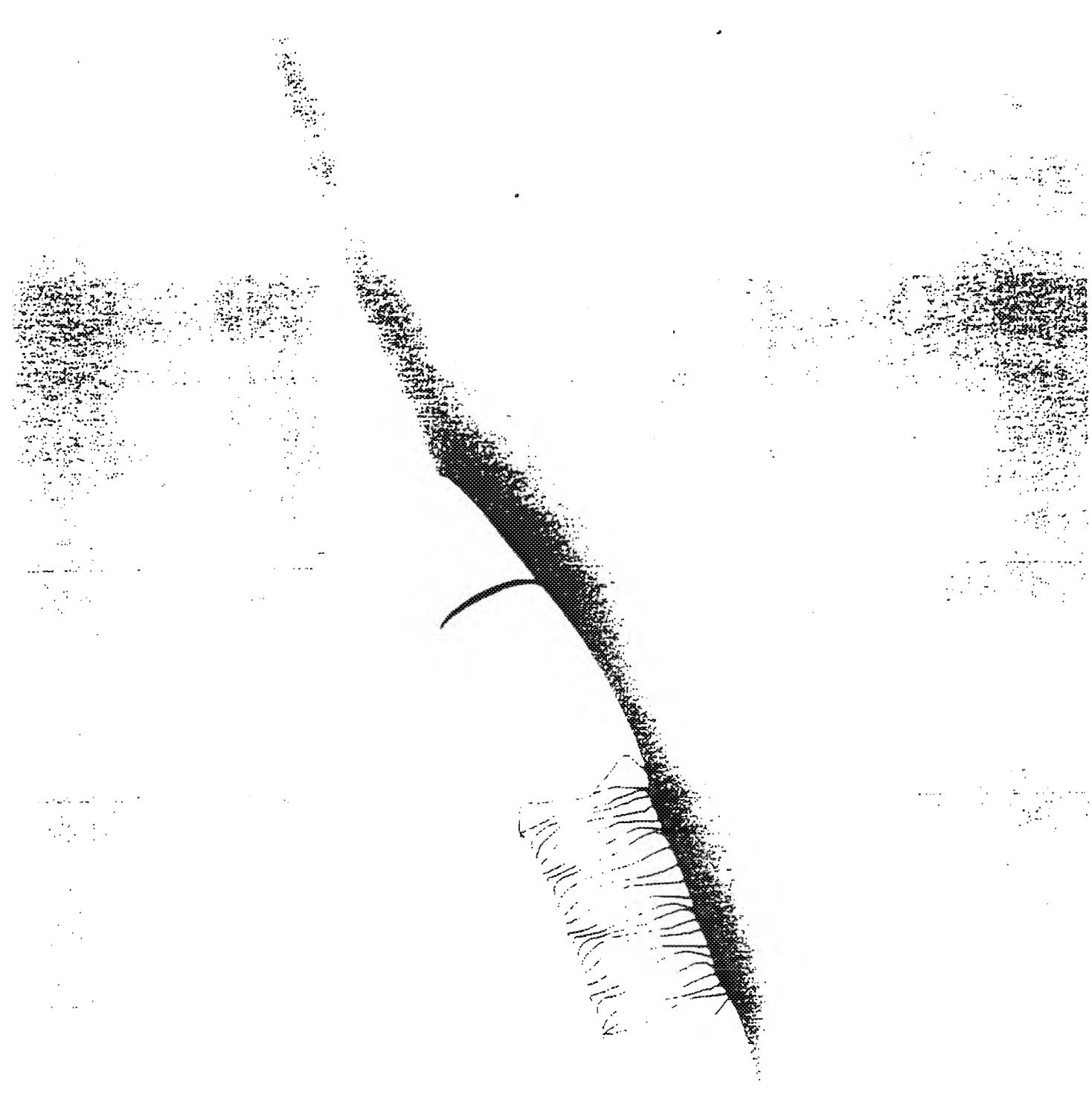
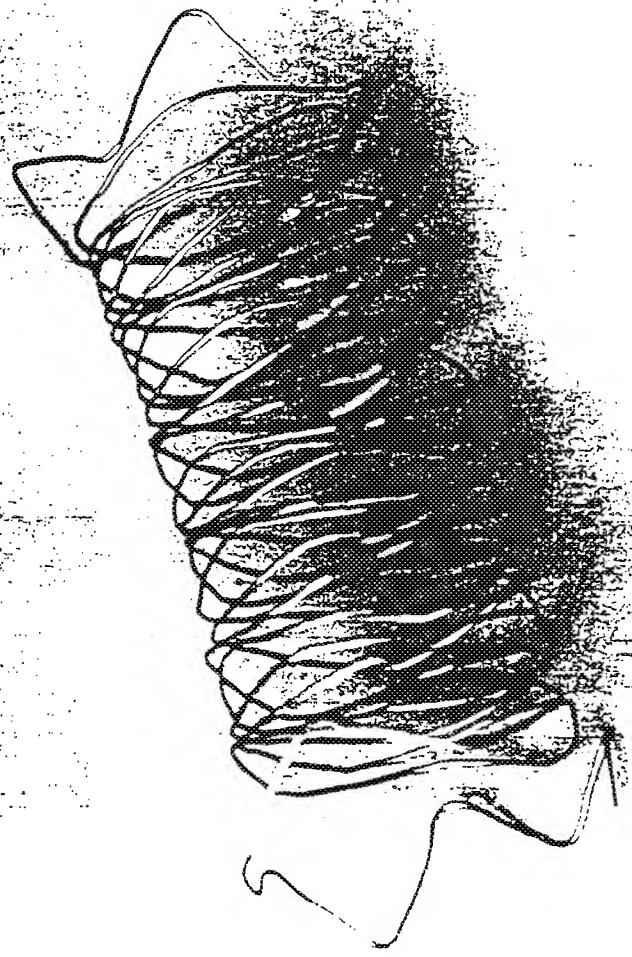


Figure 21. Ω





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Meadow	Stack Packed Steel Geometry	CONFIDENTIAL						
Design Variables:								
I ["]	1.000							
D ["] closed	0.157							
D ["] open	0.472							
R1 [psi]	10.000							
d ["]	0.010							
I ["] closed	0.020							
N	3							
M	22.47							
Outputs:								
(Eq. #)								
S1	λ ["] closed	0.166	2	0.117	\$36	Angle	-85°	-0.8755
4	A ["] closed	0.114				Values	-45°	-0.7220
9	θ ["] open	85.0		80		of (9)	25°	-0.5916
S2	θ ["] closed	13.0				Solve (θ) = 0	0°	-0.4083
1	λ ["] open	0.485				5.3768E-08	25°	-0.2231
6	A ["] open	0.010		0	28		45°	-0.1101
3	λ ["]	0.097		0	31		85°	0.0000
10	LW ["]	35.147						
	Wise stress	0.351						
11	% load	20.958						
21	T [lb]	-		0.105				
22	λ ["] 4	-		4.908E-10				
12	Po	4.223E-01						
26	W	1.02						
27	KO	0.98						
	Point A	-						
17	Vx [lb]	0.000						
17	Vx [lb]	0.041						
18	My [lb]	3.53E-04						
18	Mr [lb]	5.08E-04						
22	σ [psi]	5763						
23	ϵ [psi]	1800						
28	ϵ [psi]	6795.	≤	67.000	Load	Variables	0.974	
						cos(theta_c)	0.225	
						sin(theta_c)	0.007	
						cos(theta_o)	0.998	
						sin(theta_o)		
19	Vy [lb]	0.105						
19	Vy [lb]	0.041						
20	My ["]	0.00E+00				Equation A:		
20	Mz ["]	1.01E-03				13	0.00121641	1.4
22	σ [psi]	11000				15	0.1814E-05	1.0
23	σ [psi]	1785.				13	0.00088767	1.4
28	ϵ [psi]	11584.	≤	67.000	Load Areas and Centroids			
						Areal	0.00088767	
						A1862		
						A1863		

Minedox		Band Packed Stent Geometry		CONFIDENTIAL					
Design Variables:				% Last Optimal Values:					
L ["]	1.000	4.15 ["]		M		N		S	
D ["] closed	0.157	0.010		-25.6728		14.2		44.8	
D ["] open	0.472	0.020		-25.6728		7.1		8	
R [psi]	10.0	0.021		-25.6728		6		44.8	
d ["]	0.010								
N	12								
M	14.20								
g ["] closed	.25.8								
Output:		Equation 6:							
1	A ["] closed	0.041	B38						
4	A ["] closed	0.030							
1	A ["] open	0.124							
3	A ["] open	0.009							
5	A ["] closed	0.011							
9	A ["] open	72.8							
4	A ["] open	0.003							
10	[W ["]	27.403							
With Area:		0.274							
11	% loss	44.8							
2.1	T [(lb)]	0.168							
2.2	P [(lb)]	4.809E-10							
1.2	P [(psi)]	54.2							
2.8	M	1.02							
2.7	k0	0.98							
Point A									
1.7	Vx [lb]	0.000							
1.7	Vy [lb]	0.013							
1.8	Mx [lb]	8.91E-05							
1.8	My [lb]	2.77E-04							
2.2	[psi]	2861.							
2.3	[psi]	352.							
2.8	[psi]	3120.							
				fressa					
				87,000					
Point B									
1.8	Vx [lb]	0.186							
1.8	Vy [lb]	0.013							
2.0	Mx [lb]	0.005E-09							
2.0	My [lb]	5.54E-04							
2.2	[psi]	5813.							
2.3	[psi]	2824.							
2.8	[psi]	8173.							
				fressa					
				81,000					
Equation 6:									
				A1e1		8.71E-05		14	
				A1e2		0.00031483		16	
				A1e3		8.71E-05		14	
Equation 6:									
				cos(theta, cl)		0.902			
				sin(theta, cl)		-0.432			
				cos(theta, cp)		0.300			
				sin(theta, cp)		0.854			
Equation 6:				Load Area and Centroidic					
				Point A		Area1		0.00130687	
				Point B		Area2		0.0003	
				Point C		Area3		0.00130687	

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Name (Print)

(Signature)

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2. At the time of the invention thereof we were working for Meadox Medicals, Inc., assignee of the present application. With respect to the inventor Rudnick, I was an employee of Meadox Medicals, Inc. and with respect to inventor Wiktor, I was a consult

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- b. A confidential report entitled "Stent Analysis Summary" (Exhibit B) prepared by Product Genesis Inc., an engineering and design firm, which was retained by assignee, Meadox Medicals, Inc., to conduct an engineering analysis of the nested stent which is the subject of the claims of the present application. That report bearing a final issue date prior to April 1, 1994 (also redacted), includes a drawing labeled Figure 2-2 "Stacked Packing Geometry" showing a drawing of the nested stent of the present invention. Further and as evidence of completion of the invention, the report of Exhibit B includes photographs at Figures 4-4 through 4-7 showing the constructed nested stent of the present invention. Also as an attachment to this report are two spreadsheets showing design variables for construction of the nested stent of the present invention. Certain of these design variables have been included in the present application, being incorporated into Table 1.

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DATED: _____

James J. Rudnick

DATED: MAY 18 2000


Dominik Wiktor

A

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5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT:

Dominik M. Wiktor

James J.Rudnick

Brent Nixon

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
		Dominik M. Wiktor	4 Culin Drive Cranford, NJ 070
		James Rudnick	74 Moore Ave, Waldwick, NJ 07463

WITNESSED AND UNDERSTOOD BY:

Signature Anthony M. Spadaro Print Name Date: _____

APPROVED FOR FURTHER PATENT REVIEW:

Yes No _____ Date: _____

Yes No _____ Vice President Date: _____

EXECUTIVE COMMITTEE REVIEW:

Approved for Patentability Opinion _____ President Date: _____

Approved for Patent Application Steven Goldstein President Date: _____

Other (explain below) _____ President Date: _____

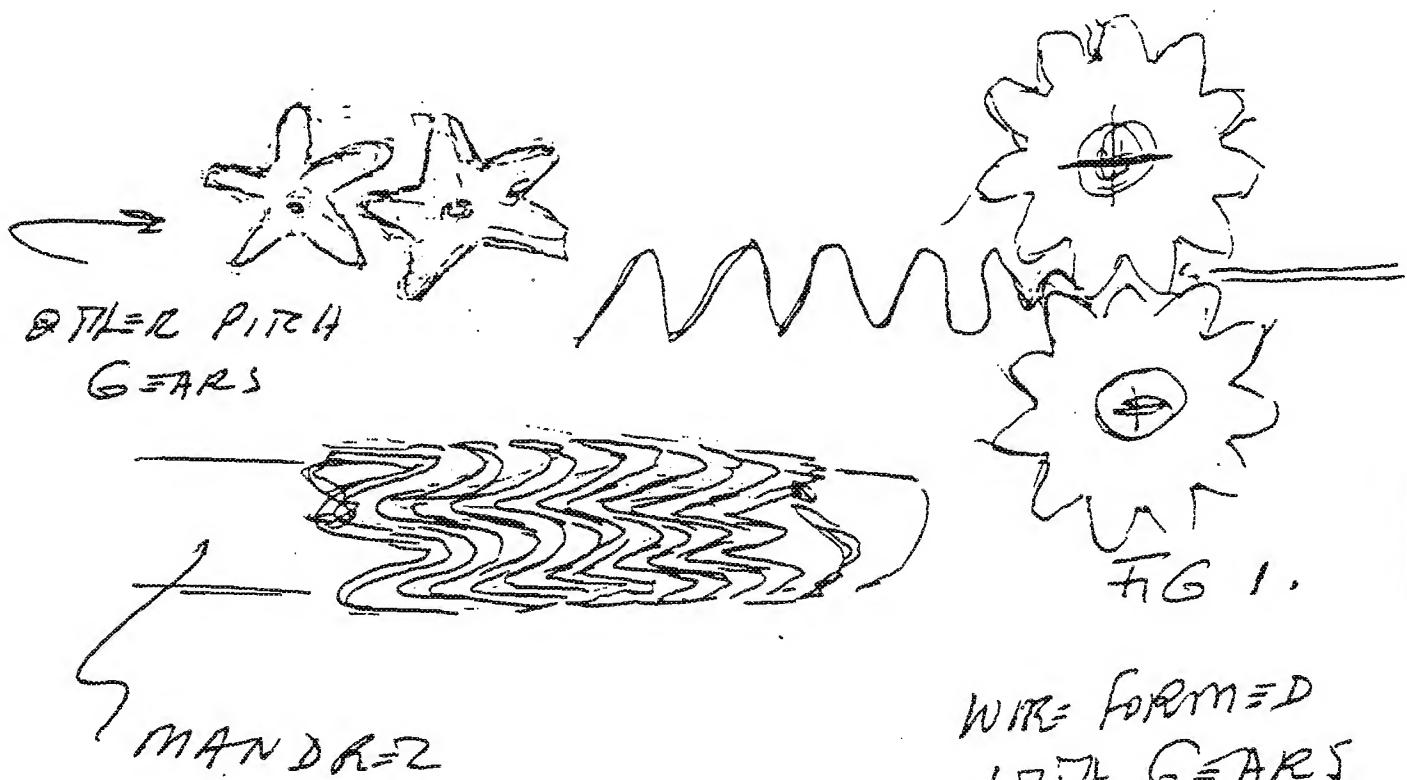
Comments: _____

BOOK NO.:	PAGE NO. <u>1</u> of <u>1</u>	PROJECT NO.:	DATE:
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SUBJECT:

HIGH STRENGTH - HIGH WIRE DENSITY
INTRAVASCULAR EXPANDABLE STENT

1. TANTALUM WIRE PREFORMED OVER GEARS



WIRE FORMED
WITH GEARS

FIG 1

James J. Rudnick
JAMES J. RUDNICK

try.
RECORDED

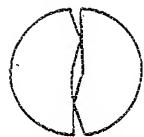
Dominic M. Niktor

INVENTOR DATE

Dominic M. Niktor

Cathy M. Niktor
WITNESS DATE





Product Genesis Inc.

Engineering Design and Product Development

300 Bent Street
Suite 200
Cambridge, MA 02141
617 661 3552
FAX 617 661 0126

Stent Analysis Summary

FINAL ISSUE

For:
Meadox/SurgiMed
112 Bauer Drive
Oakland, NJ 07436
1-800-221-1542

By:
Product Genesis, Inc.
300 Bent Street, Suite 200
Cambridge, MA 02141
617-661-3552

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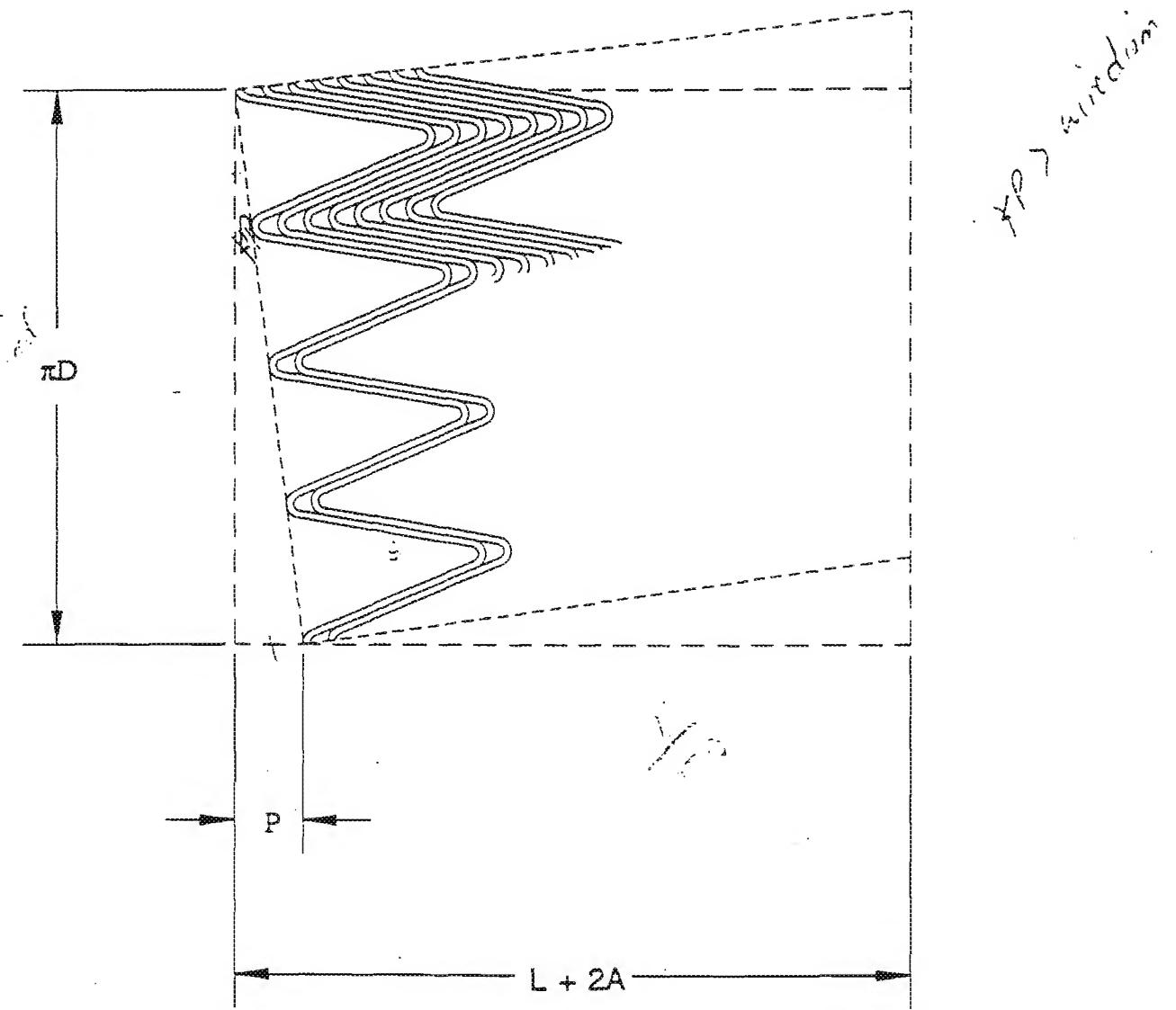
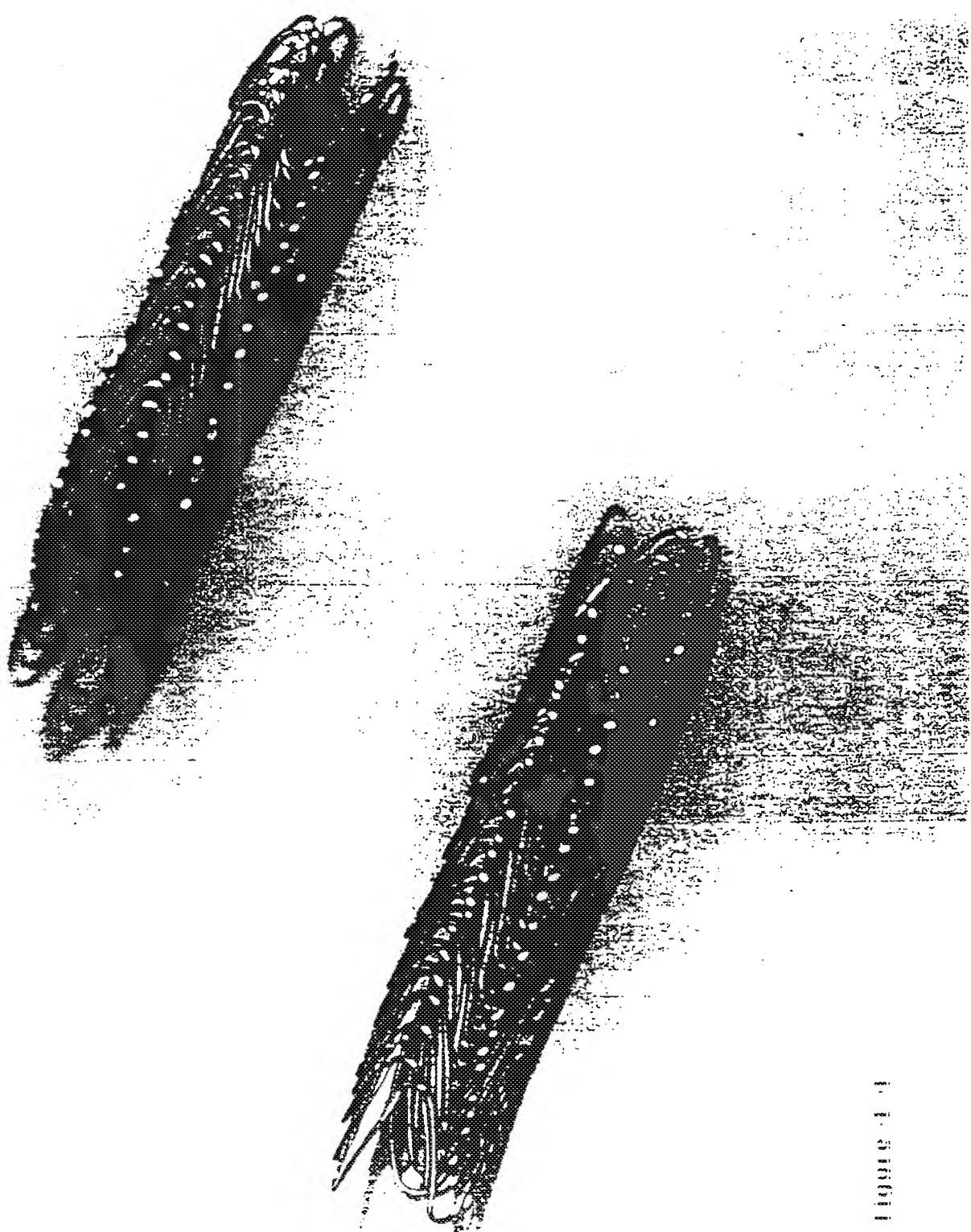
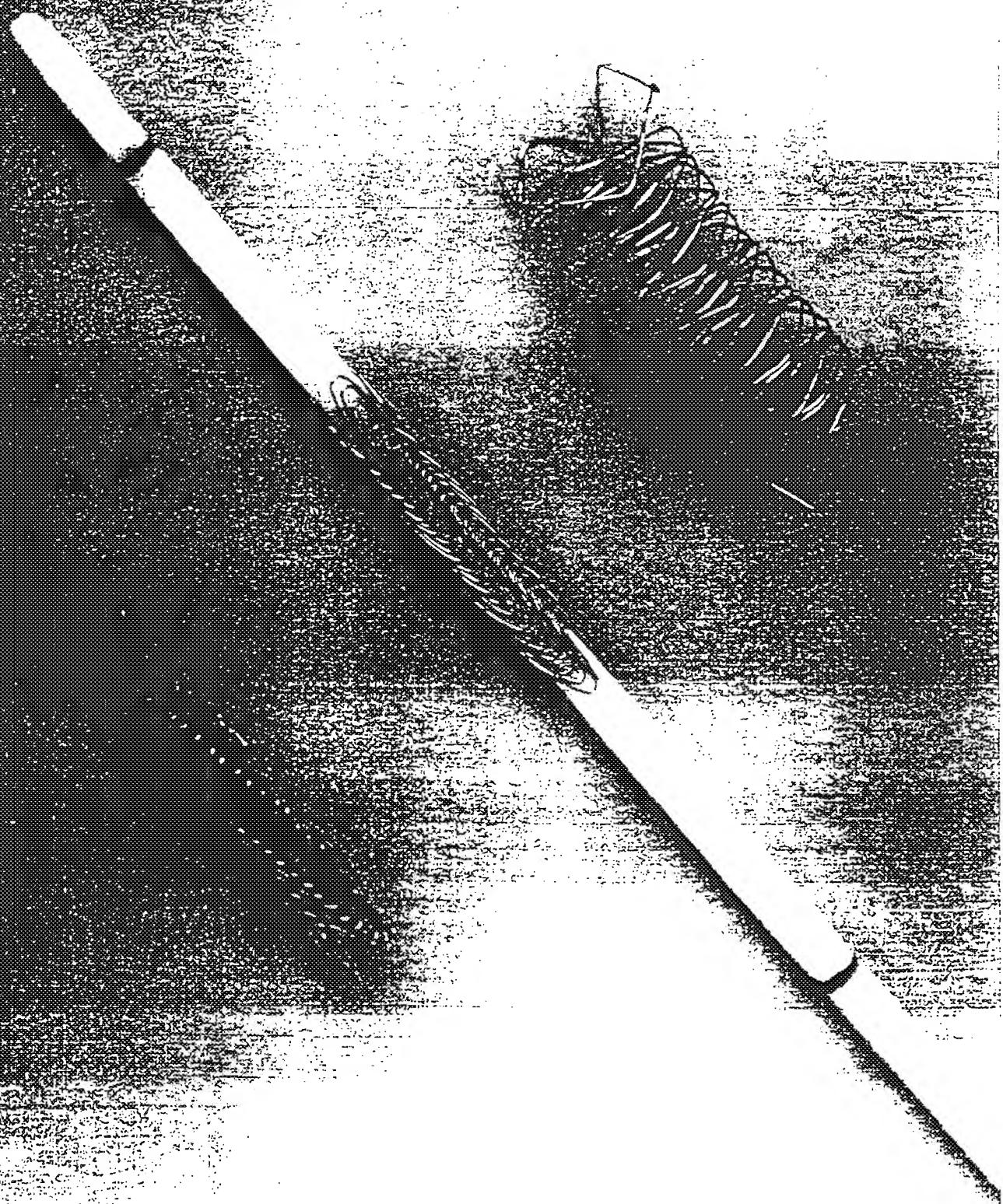


Figure 2-2: Stacked Packing Geometry

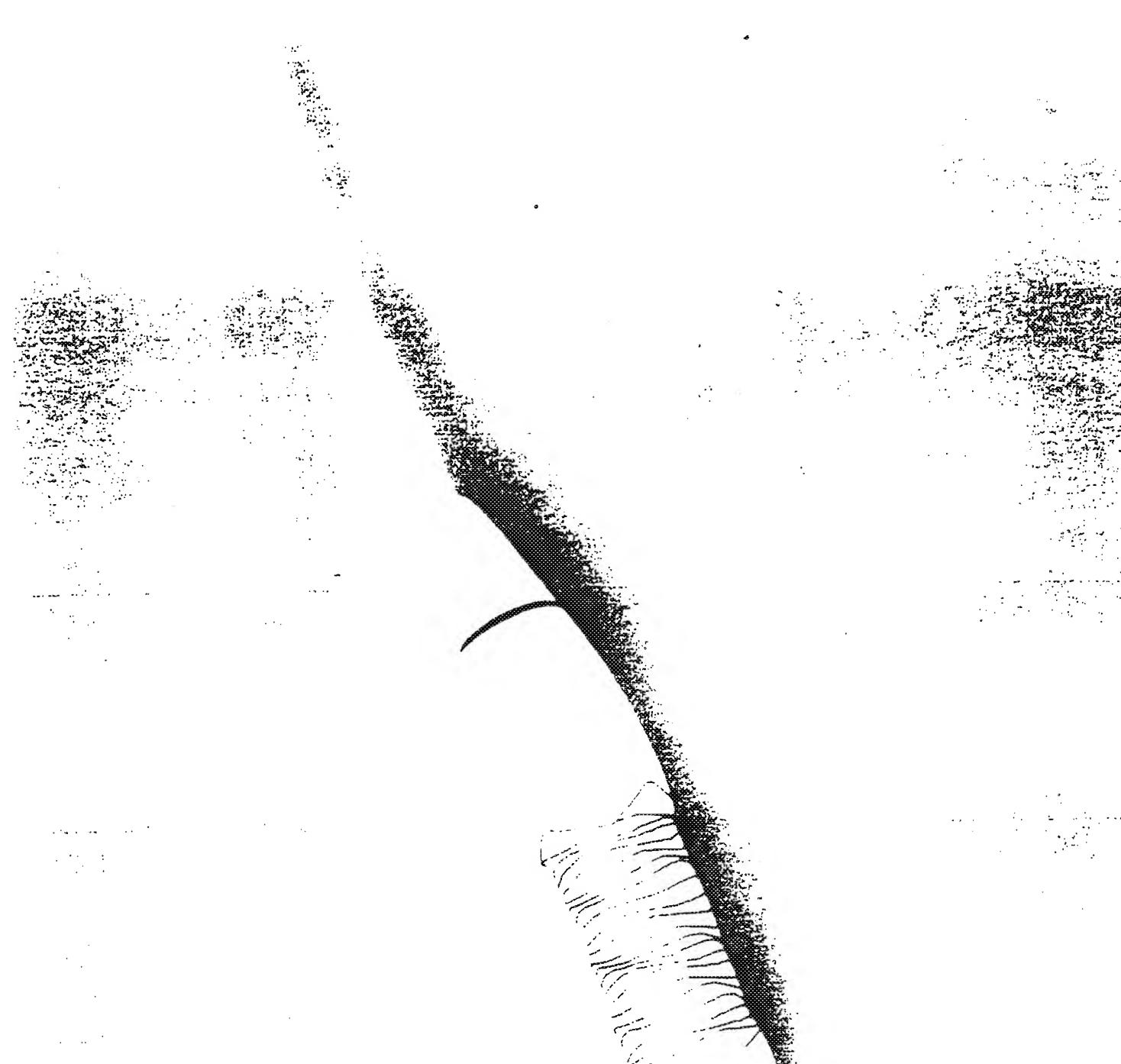


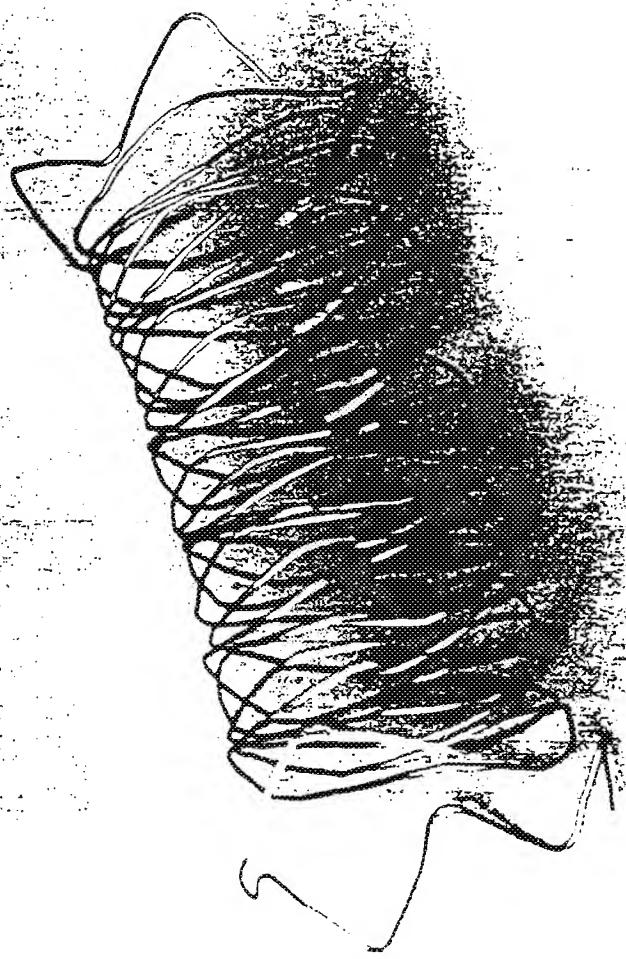
1.1.3 (iii)

Figure 4-5



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Variables		Stack Packed Stent Geometry		CONFIDENTIAL			
Design Variables:		Most Optimal Values:		N		% lost	
1	[C]	1.000		0.010	11.3	3	26.0
D	closed	0.157		0.020	13.00	2	14.7
D	open	0.472		0.020	13.10	2	2915.
P _u (psi)		10.000		0.010	10.07	4	7884.
d	[C]	0.010		0.020	13.05	3	11584.
d	[C]	0.010		0.020	15.06	2	9507.
r	closed	0.020					
N	"	3					
M	"	22.47					
Outputs: (Eq. #)		Constraints: (Eq. #)		Angle Values of [9]:		-85° -0.8755 -45° -0.7230 -25° -0.5919 0° -0.4000 25° -0.2231 45° -0.1010 65° 0.0000	
S1	1 [C] closed	0.165	2	0.117	53.88		
4	A [1] closed	0.114					
9	θ [r] open	85.0	1	9.0	8		
52	θ [1] closed	13.0					
1	A [1] open	0.485					
8	A [4] open	0.010		0	29		
3	A [3] open	0.097		0	31		
10	Lw [C]	35.147					
Value size		0.351		Stress Concentration Variables			
11	% loss	28.958		R/C	47.244		
21	V [1] (lb)	0.105		h/c	0.006		
22	V [4] (lb)	4.909E-10					
12	F _x	4.223E+01					
28	M _y	1.02					
27	ho	0.98					
Point A		Trigonometric Variables		Load Areas and Centroids			
17	V _y [lb]	0.000		cos(theta_c)	0.974		
17	V _z [lb]	0.041		sin(theta_c)	0.225		
18	M _y [lb]	3.53E-04		cos(theta_o)	0.087		
18	M _z [lb]	5.06E-04		sin(theta_o)	-0.996		
22	V [2] (lb)	5783.					
23	V [ps] (lb)	1800.					
28	V [20] (lb)	8785.	<	Area1	0.0008767	x1	0.00421841
19	V _y [lb]	0.105		Area2	2.1814E-05	x2	0.010
19	V _z [lb]	0.041		Area3	0.0008767	x3	0.00421841
20	M _y [lb]	0.00E+00					
20	M _z [lb]	1.01E-03					
Point B		Equation #:		Equation #:			
19	V _y [lb]	0.105		13	1.01E-03	15	0.00421841
19	V _z [lb]	0.041				13	1.0000
22	V [ps]	11000.					
23	V [psi]	1785.					
28	V [psi]	11584.	<				
		67,000.					

